Supreme Court, U.S.
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No. 03-1505

IN THE

Supreme Court of the United States

MARK MILLER AND CHERYL MILLER, INDIVIDUALLY, AND MARK MILLER, AS ADMINISTRATOR OF THE ESTATE OF MATTHEW MILLER, DECEASED,

Petitioners,

v.

PFIZER INC (ROERIG DIVISION),

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether this Court should review the court of appeals' decision affirming the entry of summary judgment against Petitioners when the district court (i) found the methodology used by Petitioners' causation expert unreliable and scientifically invalid; (ii) followed the recommendations of two court-appointed experts in doing so; (iii) found the opinions expressed by the expert to have been a "moving target" throughout the litigation, but nevertheless allowed him to revise his opinion numerous times and limited him only when he attempted to change his opinions yet again on the day of the *Daubert* hearing; (iv) granted summary judgment based on Petitioners' failure to adduce judicially cognizable evidence of medical causation; and (v) granted summary judgment on an alternative state-law ground independent of the failure to provide expert testimony on the medical-causation issue.

RULE 29.6 STATEMENT

Respondent Pfizer Inc ("Pfizer") is a publicly traded corporation. It has no parent corporation, and no publicly held company owns ten percent or more of its stock.

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RESPONDENT'S BRIEF IN OPPOSITION

Petitioners seek review of a narrowly fact-bound question: whether the district court abused its discretion when, against the background of the pretrial proceedings that had occurred, it enforced its own scheduling order and the requirements of Federal Rule of Civil Procedure 26(a)(2) to limit the evidence to be considered in ruling on the admissibility of a proffered expert's testimony under Federal Rules of Evidence 702 and 703. (*See* Pet. i, 13.) After carefully examining the proposed testimony of Petitioners' medical-causation expert as stated in multiple written submissions and in a two-day deposition, appointing two independent experts who then issued a de-

tailed written report finding the methodology used by Petitioners' expert unreliable and scientifically invalid, and conducting a two-day evidentiary hearing on the issue, the district court found the proposed testimony unreliable, scientifically invalid, and inadmissible. Because Petitioners had no other evidence of medical causation, the district court granted summary judgment for Pfizer.

On February 4, 2004, a unanimous panel of the United States Court of Appeals for the Tenth Circuit affirmed. Petitioners also seek review of the question whether the judgment should be reversed because of what they call a "pronouncement" by the United States Food and Drug Administration ("FDA") made on March 22, 2004 (*id.* at i), more than a month after the court of appeals' ruling, and "announcements" made by the FDA and the British Medicines Control Agency at various times more than a year after the district court's grant of summary judgment (*id.* at 1-3).

In short, Petitioners seek review of two narrowly fact-bound questions having no implications for the development of the law. In addition, there is no conflict in the lower courts on any legal issue presented by the facts of this case, and the rulings below are fully consistent with the applicable decisions of this Court.

STATEMENT OF THE CASE

Petitioners commenced this product liability action on July 27, 1999, alleging that Pfizer's prescription antidepressant Zoloft® had been sold without adequate warnings and had caused their clinically depressed son to commit suicide. On August 13, 1999, pursuant to Federal Rule of Civil Procedure 26(a)(2) and the district court's scheduling order, Petitioners disclosed that Dr. David Healy, a psychiatrist from rural North Wales in the United Kingdom, would be the expert witness whose testimony they would offer to show that Zoloft can cause suicide (general medical causation) and that it

did cause the suicide alleged in this case (specific medical causation).

Thereafter, as the district court later observed with judicial politesse, Dr. Healy's opinion on general medical causation "evolved throughout this litigation." *Miller v. Pfizer Inc*, 196 F. Supp. 2d 1062, 1066 n.10 (D. Kan. 2002). The evolution began with a supplemental report by Dr. Healy dated December 10, 1999, that, like his original report, provided no data analyses or calculations supporting his opinions. It continued with a letter report dated March 6, 2000, stating new purported bases for his opinions, again un-supported by data analyses or calculations. At his deposition on March 27 and 28, 2000, he again offered new relative-risk opinions, again unsupported by data analyses or calculations.

On April 18, 2000, within the time specified by the district court for the filing of dispositive motions, Pfizer moved, under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude Dr. Healy's medical-causation testimony. At the same time, Pfizer moved for summary judgment on the ground that, without Dr. Healy's testimony, Petitioners would have no evidence to prove general and specific medical causation. Petitioners then filed a declaration by Dr. Healy dated May 9, 2000, stating still more new purported bases for his opinions, but again unsupported by data analyses or calculations.

On August 18, 2000, the district court entered an order to show cause containing, *inter alia*, the following findings:

- "The first postulate [relied on by Dr. Healy] concerns the strength of the association between the exposure and effect. . . . [T]he court is . . . unpersuaded that Dr. Healy's heavy reliance on case reports is accepted methodology for determining the strength of the association." (Pet., Ex. 9 at 4.)

- "Koch's postulates also ask whether the association is consistent with other research. . . . Dr. Healy does not discuss other research. . . . This appears to be a misapplication of Koch's postulates." (*Id.* at 4-5.)
- "Koch's postulates provide that a scientist should rule out alternative explanations to avoid reaching an erroneous conclusion[]. . . . Dr. Healy omits this postulate from his application of Koch's postulates. . . . Further, while Dr. Healy opines that Matthew Miller would not have committed suicide but for Zoloft, his examination of Matthew Miller's medical history and psychological state appears cursory." (*Id.* at 5.)
- "This conclusion [of Dr. Healy's regarding a causal association between akathisia and suicide] can be tested, yet Dr. Healy cites no studies finding an association between akathisia and suicide." (*Id.* at 7.)

Despite these and other concerns expressed in the order regarding the unreliability and scientific invalidity of Dr. Healy's methodology, the district court, instead of granting Pfizer's *Daubert* motion, ordered the parties to "show cause in writing . . . whether the Court should employ an independent expert to assist the Court in addressing the issues raised by [that motion]." (*Id.* at 9.) In response to the order to show cause, Petitioners submitted not only a brief, but another declaration by Dr. Healy, dated August 31, 2000, purporting to address the methodological flaws and failure of proof that the district court had noted. Once again, however, Dr. Healy failed to provide data analyses or calculations.

The district court gave Petitioners another chance by appointing two independent experts—Dr. John Concato, a physician-epidemiologist from Yale Medical School, and Dr. John Davis, a neuropsychopharmacologist from the Univer-

sity of Illinois[1]—to help the court determine whether Dr. Healy's methodology was consistent with sound scientific principles. The independent experts were given Dr. Healy's deposition transcript, his reports, declarations, and exhibits, and the parties' briefing on the *Daubert* issue. *Miller v. Pfizer, Inc*, 356 F.3d 1326, 1329 (10th Cir. 2004). The district court also encouraged the independent experts to examine additional scientific and medical literature as they saw fit. *Id.*

The independent experts provided the court with their written report on September 5, 2001. It discredited Dr. Healy's methodology as unreliable and unscientific in multiple respects. *See id.* It found, for example, the following:

- His "methodology for determining medical causation has not been accepted in the relevant scientific community." *Miller v. Pfizer, Inc*, No. 99-CV-2326, 2001 WL 1793169, at *2 (D. Kan. Sept. 4, 2001).
- His "heavy reliance on case reports" was not accepted methodology for determining strength of a posited association between a drug and suicidality. "[L]ack of a comparison group would still make a series of case reports unsuitable for determining the quantitative strength of an association, regardless of other attributes." *Id.* at *2-3.
- His failure to discuss other research and demonstrate consistency with other research pertaining to his posited associations between Zoloft® and "akathisia" and between akathisia and suicide constituted misapplication of the scientific method. *Id.* at *6.

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[1] Petitioners recommended the appointment of Dr. Davis and agreed to the appointment of Dr. Concato.

- His failure to "rule out alternative explanations" for suicides temporally associated with therapy violated "a fundamental tenet of scientific reasoning." *Id.* at *4.

- His reliance on certain factual evidence and "exclusion of evidence from other sources which suggest the possibility of suicidal thoughts and behavior" that preceded and were independent of use of Zoloft® was "not generally accepted practice." *Id.* at *4-5.

- His "manner of finding a causal association between use of SSRIs and akathisia, and akathisia and suicide," was not "generally accepted by the scientific community." *Id.* at *6.

- "A threshold for level of proof [about causal relationships] is often established only after deliberation by selected members of the scientific field, as when scientific panels reach consensus. Regarding the question of SSRIs and suicide, such panels have not found the level of proof to be reached. Dr. Healy . . . holds a minority opinion in this matter. We acknowledge that a minority view (proposing causality) at one point in time may later become the majority view (that establishes causality), but that phenomenon has not, to date, occurred with regard to an association of sertraline and suicide." *Id.* at *7.

- "The data related to Dr. Healy's healthy volunteer study, as well as data from the so-called Hindmarch study, do not produce statistically significant results." *Id.* at *8.

- "[T]he available evidence does not show an increased rate of suicidal acts [or ideation] associated with SSRI agents. (The rate of suicide on SSRIs is actually decreased by approximately one-half)." *Id.* at *9.

- Dr. Healy's methods relied on unpublished data and "do not conform to generally accepted methodology" because "the numbers of patients in each group are not reported, and the statistical significance of the results . . . are not provided." *Id.* at *10.

- His "healthy volunteer study is not a sufficient basis for calculating any statistically significant relative risk, due to issues involving study design and sample size." *Id.* at *11.

- Regarding an article relied on by Dr. Healy: "As noted by the study authors, however, available data suggested that three possible confounding factors (age; antidepressant prescription switches; prior history of deliberate self-harm) contributed to an increased unadjusted relative risk [for SSRIs relative to other antidepressants]. . . . Thus, the study does not provide strong evidence for or against a possible sertraline-suicide association." *Id.* at *10.

- His "'lines of evidence' only partially satisfy Koch's postulates. . . . [and] 'confounding' has not been excluded. . . as an alternative explanation for an apparent sertraline-suicide relationship." *Id.* at *11.

Again, however, rather than granting Pfizer's *Daubert* motion at that point, the district court gave Petitioners yet another chance: it held a two-day evidentiary hearing on the motion on November 19-20, 2001. The court-appointed experts and Dr. Healy testified in response to questioning by each side's counsel, and the court-appointed experts even were permitted to engage in a dialogue with Dr. Healy to provide the court with additional information not elicited by counsel. When Petitioners and Dr. Healy attempted to introduce new relative-risk numbers purportedly based on new analyses and calculations derived from documents that Pfizer had produced to Petitioners nearly two years earlier, however,

Pfizer objected. The court sustained the objection, ruling that, under Federal Rule of Civil Procedure 26(a)(2), the time for disclosing opinions had long since passed, particularly because Dr. Healy sought to base his new opinions on information that had been produced to Petitioners before his deposition and before he had prepared and served his several supplemental written submissions. *Miller*, 356 F.3d at 1330.

After the hearing, consistent with the views of the independent experts, the district court concluded that Dr. Healy's methodology was unreliable and failed to reflect sound scientific principles. The court found that Dr. Healy had (a) misapplied or omitted six of the seven Koch's postulates (the scientific criteria comprising the methodology he claimed to have employed), (b) relied on scientifically flawed studies, (c) employed methodologies and espoused opinions not generally accepted in the relevant scientific community, and (d) simply ignored substantial evidence of alternative causes of the death in issue, including the decedent's depression and history of suicidal thoughts and expressions for many months before his treatment with Zoloft® commenced.

The district court noted that the flaws in Dr. Healy's methodology for finding general medical causation were "glaring, overwhelming and unexplained." *Miller*, 196 F. Supp. 2d at 1085. It also found that, on the subject of specific causation, Dr. Healy had given "scant attention to evidence of factors—other than Zoloft—which may have caused [decedent's] suicide. Dr. Healy's testimony on specific causation does not satisfy Rule 702 because it does not utilize sufficient facts and data and it is not the product of reliable principles and methods." *Id.* at 1087.

Because Dr. Healy's opinions were inadmissible, and because those opinions were Petitioners' only proffered evidence of medical causation, the district court granted summary judgment to Pfizer. The court also granted summary

judgment to Pfizer on the alternative ground that Petitioners could provide no facts to show that the decedent's treating physician would have changed his treatment of decedent had he received the different warnings that Petitioners advocated.

Petitioners appealed to the United States Court of Appeals for the Tenth Circuit, claiming that the district court had abused its discretion by limiting the information provided to the independent experts and by excluding Dr. Healy's testimony. *Miller*, 356 F.3d at 1331. Noting that "[t]he orderly conduct of litigation demands that expert opinions reach closure," *id.* at 1334, the court of appeals found no abuse of discretion. The court stated: "Far from improperly freezing Dr. Healy's opinions or holding him to his first Rule 26 statement, the district court allowed Dr. Healy to express revised opinions on numerous occasions. The district court exhibited patience and concern for fairness to both sides. It did not abuse its discretion." *Id.* at 1335. The court also concluded that the district court had "carefully and properly performed its gatekeeping function under *Daubert*." *Id.*

Because Petitioners had no admissible evidence of medical causation, the court of appeals held that the district court had properly granted summary judgment on that ground. The court of appeals did not rule on the district court's separate, additional basis for having granted summary judgment—namely, the absence of evidence that the allegedly inadequate warning was a proximate cause of the death in issue.

While the case was pending in the court of appeals, Petitioners filed two requests to take judicial notice of certain "facts" that they have argued in their Petition to this Court. The court of appeals denied those requests. *Id.* at 1336.

REASONS FOR DENYING THE PETITION

I. THE ISSUES PRESENTED IN THE PETITION ARE NOT OF A NATURE THAT WARRANTS DISCRETIONARY REVIEW BY THIS COURT.

The petition presents no issue that warrants review by this Court. Petitioners seek review essentially because they consider it unfair that the district court enforced its own scheduling order and Federal Rule of Civil Procedure 26(a)(2) and held Petitioners to their burden of proof under Federal Rule of Evidence 702 with respect to Dr. Healy's proposed testimony on the issue of medical causation. The petition cites no conflict among appellate court decisions, no controversial interpretation of this Court's jurisprudence, and no important issue of federal law. To the contrary, it complains of fairly commonplace *Daubert* and summary judgment rulings made unusual only by (i) the district court's patience in allowing Petitioners to make multiple supplemental submissions in an effort to provide at least minimal reliability and scientific validity to their expert's methodology, including submissions made up to two years after the expert's Rule 26(a)(2) report was due, and (ii) the district court's appointment of two independent experts to help evaluate the methodology used by Petitioners' expert.

The district court properly could have granted Pfizer's *Daubert* and summary judgment motions two years earlier, on August 18, 2000, when the court found that Petitioners had failed in several respects to show that Dr. Healy had followed the requirements of the methodology he had claimed to apply—namely, Koch's postulates—in formulating his opinions on the issue of medical causation. The district court again properly could have granted Pfizer's motions on September 5, 2001, when the court-appointed experts submitted their written report concluding that Dr. Healy's methodology was unreliable and unscientific in multiple respects. The district court's determination that it would not

allow Dr. Healy to change his opinions yet again and to ambush Pfizer's attorneys with new relative-risk numbers in support of his opinions on medical causation at the *Daubert* hearing in November 2001, more than two years after his Rule 26(a)(2) report was due, was nothing more than a straightforward—in fact, a long-delayed—enforcement of Rule 26(a)(2) and the court's own scheduling order. *See, e.g.*, Fed. R. Civ. P. 26(a)(2) advisory committee note ("[A] party will not ordinarily be permitted to use on direct examination any expert testimony not so disclosed.").

In sum, the petition does not ask this Court to review a rule of law. Instead, it asks this Court to reweigh the factual circumstances that the district court considered in deciding to enforce its own scheduling order and the timing requirements of Federal Rule of Civil Procedure 26(a)(2).

The petition also asks this Court to consider various "announcements" made by regulatory bodies more than a year after the district court had entered summary judgment and a "pronouncement" made by the FDA more than a month after the court of appeals had affirmed that judgment. Petitioners' contention apparently is that the "announcements" and "pronouncement" support Dr. Healy's proffered conclusions on the issue of medical causation.

That contention, however, rests on Petitioners' erroneous belief that the district court ruled Dr. Healy's testimony on medical causation inadmissible because his *conclusion* was incorrect. In fact, however, the court ruled his testimony inadmissible because his *methodology* was unreliable and unscientific. *See* 196 F. Supp. 2d at 1075-85. In any event, the "announcements" and "pronouncement" that Petitioners argue should be weighed in determining the reliability and scientific validity of Dr. Healy's opinions are evidence that did not even exist until long after the district court had entered its judgment. Accordingly, they cannot properly be considered as new evidence pertinent to the judgment. *See,*

e.g., Johnson v. Offshore Express, Inc., 845 F.2d 1347, 1358 (5th Cir. 1988) ("'Newly discovered evidence' under Rule 60(b)(2), however, must be evidence of facts existing at the time of the original trial." (internal citations omitted)); *Rivera v. M/T Fossarina*, 840 F.2d 152, 156 (1st Cir. 1988) ("evidence that came into existence after the court's judgment" was properly not considered in Rule 60(b) motion because it was not "newly discovered evidence" (internal citation and quotation marks omitted)); *Am. Motorists Ins. Co. v. Gen. Host Corp.*, 120 F.R.D. 129, 132 (D. Kan. 1988) (to be considered in Rule 59(e) motion, "the evidence must have existed at the time of trial, but not have been known to the movant").

Therefore, the petition should be denied because it does not present any issue that warrants this Court's attention.

II. REVIEW OF THE ISSUES PRESENTED IN THE PETITION COULD NOT CHANGE THE OUTCOME OF THIS CASE, BECAUSE THE DISTRICT COURT PROPERLY GRANTED SUMMARY JUDGMENT ON AN ADDITIONAL, ALTERNATIVE STATE-LAW GROUND.

This case also is not appropriate for review by this Court because review of the issues presented by the petition could not change the outcome of the case. Even if this Court were to grant the petition and resolve in Petitioners' favor the issues the petition raises, Petitioners still would be barred from proceeding in the district court because the district court granted summary judgment on an additional, alternative, independent ground not addressed by the petition.

To prove their case under applicable Kansas law, Petitioners had to establish that Zoloft® can cause suicide, that Zoloft® specifically caused Petitioners' decedent to commit suicide, and that the inadequate warnings were a cause in fact of the suicide. *See, e.g., Miller*, 196 F. Supp. 2d 1096, 1124

(D. Kan. 2002); *Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1045-49, 1057 (Kan. 1984). The district court properly ruled that Pfizer was entitled to summary judgment *both* because of Petitioners' failure of proof on the issue of medical causation *and* because Petitioners could not prove that the allegedly inadequate warnings were a cause in fact of the decedent's death. The latter, independent basis for the summary judgment entered below would be unaffected by any ruling on the issues presented by the petition.

Because Kansas law applies the "learned intermediary" doctrine, manufacturers of prescription drugs are only required to give warnings to medical providers, not directly to patients. *Wooderson*, 681 P.2d at 1052. Petitioners contended in the district court that inadequate Zoloft® warnings caused their decedent's death. Uncontroverted evidence showed, however, that even if the warnings accompanying the drug were inadequate, that inadequacy could not have been a cause in fact of the decedent's death. The physician who prescribed Zoloft® for the decedent provided uncontradicted testimony that he would have prescribed the medication and given the same instructions to Petitioners even if he had received the warning Petitioners claimed should have been given. That evidence broke the chain of causation and precluded any finding that the allegedly inadequate warning was a cause of the decedent's injury. *See, e.g., Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1018-19 (10th Cir. 2001); *Daniel v. Ben E. Keith Co.*, 97 F.3d 1329, 1332-33 (10th Cir. 1996). Accordingly, the district court granted summary judgment for Pfizer on this separate ground. *See Miller*, 196 F. Supp. 2d at 1126-30.

After affirming the district court's ruling with respect to the Healy testimony and the related grant of summary judgment, the Tenth Circuit did not reach the alternative summary judgment ruling based on the absence of proof of causation in fact. If this Court were to rule in favor of

Petitioners here, however, the Tenth Circuit would merely affirm the grant of summary judgment on the alternative basis. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 977-78 (10th Cir. 2001); *Eck*, 256 F.3d at 1018-19; *Daniel*, 97 F.3d at 1332-33; *see also, e.g., Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003-04 (4th Cir. 1992); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991).

Because another issue in this case would preclude Petitioners from going forward even if this Court were to rule in Petitioners' favor on the issues presented in the petition, there is no good reason for this Court to grant review.

III. THE DISTRICT COURT PROPERLY APPLIED THIS COURT'S PRECEDENTS AND FEDERAL RULE OF CIVIL PROCEDURE 26(a)(2).

In addition to presenting run-of-the-mill procedural and *Daubert* issues and ignoring the alternative basis for summary judgment, the petition fails to show any error by the district court or by the unanimous Tenth Circuit panel.

A. The District Court Did Not Abuse Its Discretion in Applying *Daubert* and Its Progeny.

The district court exhaustively reviewed Dr. Healy's various opinions, supporting documentation, and testimony. After that careful review, and with the benefit of testimony and a written report from two independent experts, the court ruled that Dr. Healy's methodology was unreliable and scientifically invalid. The court of appeals affirmed that ruling, and properly so.

This Court has made clear that "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Thus, reviewing courts must apply a deferential

abuse-of-discretion standard in reviewing a trial court's evidentiary decision. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997).

Here, the court of appeals held that the district court had not abused its discretion in applying *Daubert* principles. *See Miller*, 356 F.3d at 1335. Indeed, the court of appeals found that the district court had "carefully followed *Daubert* in determining whether Dr. Healy's opinions were founded on scientific principles," had done a "thorough" job, and had "properly performed its gatekeeping function." *Id.*

In the face of the district court's learned, detailed 32-page *Daubert* opinion and the court of appeals' approving review of that opinion, the best argument the petition can muster is that two other courts have allowed Dr. Healy to testify in other cases involving other drugs. (*See* Pet. 4, 6-7.) That argument fails both legally and factually.

Legally, even if the district court's ruling in this case were inconsistent with another district court's ruling in another case, the inconsistency would not signify any problem. It is well established that different courts may reasonably reach different results in evaluating the admissibility of expert testimony, and such differences do not reflect an abuse of discretion. *See, e.g., Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1206 (10th Cir.) ("*Daubert's* effort to safeguard the reliability of science in the courtroom may produce a counter-intuitive effect: different courts relying on . . . essentially the same science may reach different results."), *cert. denied*, 537 U.S. 1088 (2002).

Factually, the district court's decision here is not inconsistent with either of the two decisions cited by Petitioners in which Dr. Healy was allowed to testify. Neither in their petition nor in the courts below have Petitioners even attempted to show that the methodology used and conclusions reached by Dr. Healy in this case are the same as the

methodology used and the conclusions reached in those other cases. Nor could they have made such a showing. The two cases in which Dr. Healy was allowed to testify involved drugs other than Zoloft®, drugs with different chemical make-ups, different clinical trial results, different pharmacological properties, and different side-effect profiles.[2] It is well established that even slightly different chemical compounds can have different effects, and imputing the effects of one to another does not meet *Daubert's* reliability requirement. *See Hollander*, 289 F.3d at 1207. Moreover, by his own admission, Dr. Healy's opinions in this case differ significantly from those he gave in the other cases.

B. The District Court Did Not Abuse Its Discretion by Precluding Petitioners' Expert Witness from Springing New Purported Bases for His Medical-Causation Opinions on the Day of the *Daubert* Hearing and After Having Withheld Them from His Rule 26(a)(2) Report, from All of His Supplemental Submissions, and from His Deposition Testimony.

The district court recognized that Dr. Healy had made his opinions a "moving target throughout this litigation." Nevertheless, the court patiently allowed Dr. Healy to revise his opinions numerous times. The independent experts and the district court considered all of Dr. Healy's revisions up until the time of the *Daubert* hearing in November 2001. Only then did the district court draw the line and refuse to allow him to spring new opinions that he had withheld from his

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[2] One of the opinions cited by Petitioners is an unpublished opinion in *Cassidy v. Eli Lilly & Co.*, Civil Action No. 821 (W.D. Pa. May 30, 2002). The drug involved in that case was Prozac. The other opinion cited by Petitioners is in *Estates of Tobin by Tobin v. SmithKline Beecham Pharmaceuticals*, 164 F. Supp. 2d 1278 (D. Wyo. 2001). The drug in that case was Paxil.

Rule 26(a)(2) report, from all of his supplemental written submissions, and from his deposition testimony.

At the *Daubert* hearing and in a filing after the hearing, Petitioners attempted to introduce new calculations and graphs prepared by Dr. Healy. The new opinion evidence was based on evidence that Pfizer had produced to Petitioners nearly two years before the *Daubert* hearing. The district court found that "[a]ny calculations that . . . Dr. Healy wanted to make from this report could—and should—have been made *well before* this point in the litigation." *Miller*, 196 F. Supp. 2d at 1091 (emphasis in original). The court further noted that "Plaintiffs' counsel admitted that the graphs and calculations which he sought to introduce were not based on new scientific developments or new information from the experts." *Id.*

The district court properly recognized that the Federal Rules of Civil Procedure prohibit a party from making its expert's opinions a "moving target" that constantly evolves. The rules require that all bases for expert opinions be timely disclosed under Rule 26(a)(2) or they are inadmissible, absent substantial justification. *See* Fed. R. Civ. P. 26(a)(2) and advisory committee notes; Fed. R. Civ. P. 37(c)(1). The district court acted within its discretion in excluding Petitioners' untimely efforts to introduce new opinions by Dr. Healy proffered years *after* completion of the Rule 26(a)(2) disclosures, *after* Pfizer's *Daubert* motion and summary judgment motion had been fully briefed, and *after* the court-appointed experts had spent months evaluating the methodology and opinions in Dr. Healy's multiple written submissions and in his two-day deposition. *See, e.g., Miller*, 356 F.3d at 1334; *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 953-54 (10th Cir.), *cert. denied*, 537 U.S. 1066 (2002); *Lohnes v. Level 3 Communications, Inc.*, 272 F.3d 49, 59-61 (1st Cir. 2001) (affirming exclusion of untimely disclosed expert affidavit submitted in response to summary judgment motion and stating

that "expert disclosure requirements are not merely aspirational, and courts must deal decisively with a party's failure to adhere to them").

The district court's ruling also comports with this Court's recognition in *Daubert* that, while science can evolve over time, the law must make final determinations based on the evidence at a given point.

> It is true that open debate is an essential part of both legal and scientific analyses. Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. *Law, on the other hand, must resolve disputes finally and quickly.* The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence *designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.*

Daubert, 509 U.S. at 596-97 (emphasis added). The need for finality in legal disputes involving "evolving" scientific research has been recognized by courts of appeals as well. *See, e.g., Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1322 (11th Cir. 1999); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) (noting that "the courtroom is not the place for scientific guesswork, even of the inspired sort"). Judge Posner's statement that "[l]aw lags science; it does not

lead it," *Rosen*, 78 F.3d at 319, succinctly summarizes the reality that Petitioners are unwilling to concede.[3]

The Federal Rules of Civil Procedure and the rulings of this Court make clear that the law must evaluate a scientific opinion at a fixed point in time and cannot allow that opinion to change constantly until final judgment has been entered. This is so because our system is designed to "reach[] a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past." *Daubert*, 509 U.S. at 597. The district court carefully followed the Federal Rules of Civil Procedure and the dictates of this Court in fixing Petitioners' expert testimony at a point in time nearly two years after the date specified for expert disclosures. There was no abuse of discretion.

IV. THE FACTUAL ISSUES RAISED BY PETITIONERS PROVIDE NO BASIS FOR REVIEW.

Finally, Petitioners ask the Court to grant their petition because of purportedly "new" factual issues they seek to raise. As a general matter, factual issues rarely justify review by this Court. In this case, they most certainly do not.

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[3] Petitioners' selective quotation of Justice Breyer's remarks in the *Reference Manual on Scientific Evidence* (2d ed.), (*see* Pet. at 7-8), paints a misleading picture that is inconsistent with the principle of finality adopted by this Court in *Daubert*. Justice Breyer's views expressed in the introduction are consistent with the lower court rulings in this case. Justice Breyer wrote, "Our objective is to avoid legal decisions that reflect . . . so-called science. The law must seek decisions that fall within the boundaries of scientifically sound knowledge." *Reference Manual on Scientific Evidence* at 4 (2d ed. 2000). Furthermore, "[d]espite the difficulties, . . . there is an increasingly important need for law to reflect sound science." *Id.* at 5. An expert opinion that two eminent court-appointed experts found was not based on good science does not fall within the bounds of "scientifically sound knowledge" or "sound science."

Petitioners' theory seems to be that additional factual developments have occurred since the *Daubert* hearing that may change the district court's evaluation of Dr. Healy's opinions. Petitioners are wrong on both the law and the facts. Dr. Healy's opinions offered in the case were based on flawed methodology and junk science. That was the case in 2001, and it is still the case today. The methodology and junk science he in fact applied from 1999 to 2001 in this case have not subsequently changed, nor is it even possible for them to have done so, regardless of what may have happened in the world thereafter. He did what he did.

Furthermore, the alleged factual developments cited by Petitioners address only the issue of general medical causation. Dr. Healy's opinions regarding specific causation gave "scant attention to evidence of factors—other than Zoloft—which may have caused [decedent's] suicide. Dr. Healy's testimony on specific causation does not satisfy Rule 702 because it does not utilize sufficient facts and data and it is not the product of reliable principles and methods." *Miller*, 196 F. Supp. 2d at 1087. No announcement or pronouncement by the FDA or anyone else can change this.

Moreover, the recent FDA statements relied on by Petitioners do not, contrary to Petitioners' suggestion, establish general medical causation in this or any other case. The FDA's document attached as Exhibit 5 to Petitioner's Appendix states that "FDA has *not concluded that these drugs cause worsening depression or suicidality*, [but that] health care providers should be aware that worsening symptoms could be due to the underlying disease or *might* be a result of drug therapy." (Emphasis added.) Thus, the FDA has *not* concluded that general causation exists; rather, it has merely provided a precautionary measure that provides no support to Dr. Healy's conclusion, much less to his methodology. *See, e.g., Hollander*, 289 F.3d at 1215 (citing *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)).

As the Tenth Circuit noted in similar circumstances in *Hollander*, "differing standards militate against applying regulatory actions to the elements of tort law." 289 F.3d at 1215 (citing *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 n.3 (10th Cir. 1999)). The fact that the government says that a drug *might* cause a certain reaction does not establish general causation for tort purposes.

Finally, as noted above, reversing the district court on the expert issue would not change the outcome of this case, since the very warnings alleged by Plaintiffs (and that Petitioners erroneously contend are involved in the Food and Drug Administration's recent pronouncements upon which Petitioners rely) were based on information well-known to the prescribing doctor in the case and would not have changed anything that the doctor did for the decedent or any of the warnings that he gave. Accordingly, the Court should deny the petition.[4]

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[4] Petitioners' suggestion that this case is appropriate for GVR misunderstands that doctrine. Typically, that procedure is employed when there has been some intervening Supreme Court precedent or legal development that justifies granting the petition, vacating the judgment, and remanding the case. *See Lawrence ex. rel. Lawrence v. Chater*, 516 U.S. 163, 165-66 (1996).

> Where intervening developments, or recent developments that [the Court has] reason to believe the court below did not fully consider, reveal a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration, and where it appears that such a redetermination may determine the ultimate outcome of the litigation, a GVR order is . . . potentially appropriate.

Id. at 167. Here, there is no reasonable probability that the district court would change its exhaustive analysis and decision based on the new "evidence," nor is there any chance that a changed decision on general medical causation would affect the district court's decision on specific causation or causation in fact. Thus, "the delay and further cost entailed in a remand are not justified by the potential benefits of further consideration by the lower court, [and] a GVR order is inappropriate." *Id.* at 168.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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